REMARKS

This Response is to the non-final Office Action mailed September 29, 2005. Claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37 are pending in this application and stand rejected, with Claims 2 to 4, 15, 16, 22, 28 and 31 having been previously canceled without prejudice or disclaimer. In this Response, the specification has been amended slightly to add Fig. 4 to the Brief Description of the Figures. Claims 6, 13, 19 and 20 have been amended as discussed in more detail below. No new matter has been introduced via any of the amendments. Applicants submit that no fees are required in connection with this Response, however, please charge Deposition Account No. 02-1818 for any insufficiency of payment, excluding the issue fee, during the prosecution of this application.

In the Office Action, the drawings were objected to under 37 C.F.R. §1.83(a) for failing to show every feature of the invention specified in the claims. Claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. Claims 13, 14 and 19 to 21 were rejected under 35 U.S.C. §112, second paragraph, for failing to point out and distinctly claim Applicants' invention. Claims 1, 5 to 11, 13, 14 and 17 to 21 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,036,859 to Brown ("*Brown*"). Claims 27 and 30 were rejected under 35 U.S.C. §103(a) as being obvious in view of *Brown*. Claim 12 was rejected under 35 U.S.C. §103(a) as being obvious in view of *Brown* and U.S. Patent No. 6,445,304 to Bandeian et al. ("*Bandeian*"). Claims 23 to 26 and 32 to 37 were rejected under 35 U.S.C. §103(a) as being obvious in view of *Brown* and WO99/24145 to Kjellstrand ("*Kjellstrand*").

Regarding the drawing objection, Applicants direct the Patent Office to the Response submitted on November 21, 2003 and to Fig. 4 attached thereto. The subsequent Office Action sent February 13, 2004, indicated that Fig. 4 filed on November 24, 2003, was accepted. A note on Page 3 of that Office Action indicates that the drawing and corresponding text were sufficient to overcome the prior objection to the drawings. The next Office Action sent October 4, 2005, also did not object to the drawings. A telephone conversation with the Examiner on November 3, 2005, confirmed that an incomplete file had been transferred to the Examiner and that the drawings including Fig. 4 are proper at this time.

Regarding the rejection of claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37 under 35 U.S.C. §112, first paragraph, Applicants direct the Patent Office to the following text beginning at page 11, line 25 of the originally filed specification:

> In an embodiment, the sensor 50 preferably includes a capacitive sensor that includes a single electrode formed in a sheet or plate configuration. The electrode is preferably made of copper. As the capacitance of the absorbent pad increases due to the presence of blood, the single electrode capacitive sensor can detect the increased capacitance of blood as compared to air (i.e., no blood present) due to the coupling of field lines between the electrode and the ground of the sensor. The non-contact nature of this type of sensor is desirable because cleaning of the sensor after use can be effectively minimized or avoided as previously discussed.
>
> Applicants have surprisingly found that the capacitive sensor can detect wetness due to the presence of blood, for example, in an absorbent pad overlying the needle, with a high degree of sensitivity and specificity to needle dislodgement *without contacting the absorbent pad and for that matter blood.* In this regard, the sensor is capable of detecting an increased capacitance of the blood-wetted absorbent pad which results from its large dielectric constant as compared to a dry absorbent pad. This can be done by measuring the charging and discharging times of the electrode or by measuring the change in the dielectric constant due to the presence of blood in other known and suitable ways. [emphasis added]

Applicants submit respectfully that the above-quoted text shows that claim language directed to the sensor not contacting blood *is* described in the specification as filed originally and that the §112, first paragraph, rejection should be withdrawn accordingly.

Regarding the rejection of claims 13, 14 and 19 to 21 under 35 U.S.C. §112, second paragraph, Applicants respectfully submit that the amendments to Claims 13 and 19 overcome this rejection. Any ambiguity regarding the existence of multiple pads has been eliminated.

Regarding the rejection of claims 1, 5 to 11, 13, 14 and 17 to 21 over *Brown*, the disclosure of *Brown* makes clear that the electrodes of the sensor **contact** the fluid to be sensed, which is urine in many examples of that patent. For example, in the Abstract *Brown* states:

> An indicator box is carried by the user and coupled to the sensing pad for *generating a digitally encoded signal when urine moistens the pad and completes a circuit which includes the electrodes.* Either a local alarm or remote signal is triggered by the indicator. [Emphasis added]

In the Summary of the Invention, *Brown* states:

> The present invention is a urine sensor which is attached to a user for detecting flow of urine or other liquids from the user. *The sensor includes first and second separated electrodes which form a portion of an electrical circuit path. The pressure of liquid between the electrodes completes the electrical circuit, and causes a transmitter to generate and send a digitally encoded signal* which indicates that urination has occurred. [Emphasis added, col. 2, line 21]

In the Detailed Description, *Brown* states:

An indicator unit 20 is attached to pad 11 *and emits a signal when pad 11 is moistened.* [Emphasis added, col. 3, line 59]

Again in the Detailed Description, *Brown* states:

> In the embodiment shown in FIGS. 1-3, audible, visual and/or other indicating *signals may be emitted when urine moistens the path between electrodes 14, 16 of pad 11.* [Emphasis added, col. 4, line 41]

Brown does not appear to teach or suggest a capacitive sensor and instead teaches the simple making of a circuit via the conductive fluid contacting two electrodes that are otherwise electrically separated. *Brown* does not appear to teach or suggest a sensor that does *not* contact the fluid to be sensed and instead explicitly and repeatedly teaches that its device *requires* contact between the fluid and the electrodes of the sensor.

Applicants accordingly respectfully submit that independent claims 1, 11 and 17 and the claims depending from claims 1, 11 and 17 are accordingly patentable over *Brown* and in condition for allowance at this time.

Brown also does not disclose, teach or suggest many of the dependent claims. For example, *Brown* does not teach or suggest the capacitive sensor being located within the sensor holder such that the sensor detects wetness due to blood loss in the barrier pad as called for in claim 6. *Brown* does not teach or suggest the apparatus of claims 8 and 9. *Brown* does not teach or suggest the venous needle of claim 10. *Brown* does not teach or suggest the apparatus of claim 12, wherein the electrode comprises a single plate electrode. *Brown* does not teach or suggest claim 13. *Brown* does not teach or suggest a sensor holder having a flexible material conforming to a vascular access region as called for in Claim 14. *Brown* does not teach or

suggest the elements of dependent claims 18 to 26. These claims supply additional patentable features over *Brown*.

The patentability of claim 11 renders moot the obviousness rejection of claim 12 in further view of *Bandeian*.

Regarding the obviousness rejection of independent claims 27, 30 and 36 in view of *Brown* (claims 27 and 30) and *Brown* in combination with *Kjellstrand* (claim 36), a prima facie case of obviousness has not been shown because neither *Brown* nor any other reference cited discloses, teaches or suggests: (i) a capacitive sensor (*Brown* instead teaches the simple making of a circuit via the conductive fluid contacting two electrodes that are otherwise electrically separated); or (ii) a sensor that does *not* contact the fluid to be sensed (*Brown* instead explicitly and repeatedly teaches that its device *requires* contact between the fluid and the electrodes of the sensor). *Kjellstrand* is cited only to show an extracorporeal circuit with a blood line separation warning device.

Applicants accordingly respectfully submit that independent claims 27, 30 and 36 and the claims depending from claims 27, 30 and 36 are patentable over *Brown* and *Kjellstrand*.

Regarding the amendments, none of the amendments to claims 6, 13, 19 and 20 is narrowing or disclaims any subject matter over the art of record. The amendment to claim 6 broadens its dependency from claim 5 to claim 1. The amendments to claims 13 and 19 remove elements, broadening the claims. Support for the amendment to claim 20 can be found in the original specification for example in the text quoted above.

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,
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